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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,753	05/14/2001	N. Torben Bech-Hansen	45499.2	6888

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,753

Applicant(s)

BECH-HANSEN, N. TORBEN

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 *oc*
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 11 is acknowledged.

Claims 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 11.

Claims 1-14 are under examination in the instant office action.

Drawings

2. The figures of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For example, the two pages of Figure 3 in the instant specification should be renumbered "Figure 3A" – "Figure 3C" rather than "Figure 3, a and b and Figure 3, continued". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 3 is divided into Figures 3A-3C, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

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3. It is noted that Figures 3 and 7 of the instant application is not in compliance with the rules of sequences presented in drawing figures (see MPEP 2422.02). Appropriate correction is required.

Specification

4. Pages 31-33 include list of references cited. It is suggested that references be included in the text of the specification. If Applicant adopts this suggestion a substitute specification will be required.

5. The use of the trademarks has been noted in this application, see pages 15, 21, 24, 25, 27, 28, 29 and 30. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to carefully check the whole text of the specification for other possible trademarks.

6. On page 26, line 16, "know" should be "known", perhaps. On the same page, line 17 "moved", should be "move", perhaps.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 and 9-14 are directed to an isolated DNA molecule encoding a mammalian GPI-anchored small leucine-rich proteoglycan, or murine DNA, or DNA encoding nyctalopin, or encoding the amino acid sequence of SEQ ID NO:2 with conservative amino acid substitutions, or is homologous to SEQ ID NO:1, or is a genomic DNA. However, the instant specification fails to describe the entire genus of DNA molecules which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule of SEQ ID NO:1 and degenerate variants thereof, which encode a protein which has the amino acid sequence of SEQ ID NO:2. The subject matter, which is claimed, is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are an isolated DNA molecule encoding a mammalian GPI-anchored small leucine-rich proteoglycan, or murine DNA, or DNA encoding nyctalopin, or encoding the amino acid sequence of SEQ ID NO:2 with conservative amino acid substitutions, or is homologous to SEQ ID NO:1, or is a genomic DNA. First, the claims are not limited to a DNA molecule with a

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specific nucleic acid sequence. The claims only require the DNA to share some degree of similarity to the isolated nucleic acid molecule of SEQ ID NO:1. The specification only describes a DNA molecule having the nucleic acid sequence of SEQ ID NO:1 and fails to teach or describe any other DNA which lacks the nucleic acid sequence of SEQ ID NO:1 and encodes a protein which has functional characteristics of a polypeptide of SEQ ID NO:2. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the genus DNA molecules encoding SEQ ID NO:2. The specification does not provide a complete structure of those isolated DNA molecules that encode a mammalian GPI-anchored small leucine-rich proteoglycan, or murine DNA, or DNA encoding nyctalopin, or encode the amino acid sequence of SEQ ID NO:2 with conservative amino acid substitutions, or are homologous to SEQ ID NO:1, or of a genomic DNA. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize

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applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (an isolated DNA molecule encoding a mammalian GPI-anchored small leucine-rich proteoglycan, or murine DNA, or DNA encoding nyctalopin, or encodes the amino acid sequence of SEQ ID NO:2 with conservative amino acid substitutions, or is homologous to SEQ ID NO:1, or is a genomic DNA) because the specification teaches only the one embodiment of SEQ ID NO:1. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Claims 1-7 and 9-14 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA molecule having the nucleotide sequence of SEQ ID NO:1, does not reasonably provide enablement for any other DNA molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-7 and 9-14 are broadly drawn to an isolated DNA molecule encoding a mammalian GPI-anchored small leucine-rich proteoglycan, or encoding nyctalopin, or DNA molecule encoding the amino acid sequence of SEQ ID NO:2 with conservative amino acid substitutions, or to DNA molecule homologous to SEQ ID NO:1, or to a genomic DNA. However, the instant specification fails to provide enough guidance for the production of any nucleic acid molecule other than a nucleic acid molecule encoding SEQ ID NO:2 or a specific

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portion of SEQ ID NO:2. Therefore, undue experimentation is required to discover how to make and use the full scope of Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. In re Wands, 8 USPQ2d, 1400 (CAFC 1988).

The instant specification discloses adequate enablement for only one embodiment of nucleic acid molecule of SEQ ID NO:1, which encodes a polypeptide of SEQ ID NO:2. The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that following the disclosed protocol one skilled in the art would expect to make a DNA molecule different from a DNA molecule of SEQ ID NO:1. There is no guidance provided as how to alter the disclosed DNA molecule of SEQ ID NO:1 that would still encode a protein with a predictable functional characteristics of a protein of SEQ ID NO:2. The art on altering amino acid sequences of polypeptides and retaining the desired functions is very unpredictable. For example, it is well known in the art that changing even one amino acid in a sequence could drastically alter the properties of a protein (Introduction to proteins and protein engineering, 1986, Elsevier, p.41). Two-amino acid substitution in a polypeptide sequence could lead to completely opposite set of functions in proteins (see Yan et al., 2000, Science, 290, pp.523-527, specifically abstract and the whole paper). Therefore, without knowing specific molecular structure of the claimed DNA molecules, those that encode a mammalian GPI-

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anchored small leucine-rich proteoglycan, or encode nyctalopin, or a DNA molecule that encodes the amino acid sequence of SEQ ID NO:2 with conservative amino acid substitutions, or genomic DNA, one skilled in the art would not be able to practice the claimed invention without undue experimentation. The only one working example that is present in the instant specification is the embodiment of SEQ ID NO:1.

Thus, in view of the lack of teachings and unpredictability of the art set forth earlier, and also the absence of the working examples, the instant specification is found to be enabling only for a DNA molecule of SEQ ID NO:1. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to make and use the full scope of Applicants' invention as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claims 1, 9 and 10 are indefinite for recitation of "synthetic DNA" or "synthetic nucleic acids". As far as it is known all DNA molecules are "synthetic". Clarification is required.
11. Claim 2 is vague and ambiguous because it is not clear how an isolated DNA can be expressed in tissues.
12. Claim 9 is indefinite for the following reasons.

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation polynucleotide, and the claim also recites DNA molecule which is the narrower statement of the range/limitation.

Claim 9 is further indefinite for recitation "substantially homologous". Term "substantially" is a relative term and metes and bound of "substantial" cannot be defined from the claim.

Finally, claim is indefinite for recitation of "stringent" hybridization conditions. The limitation "stringent conditions" is conditional and the defining conditions are not recited in the claim or the specification.

13. Claim 11 is vague because it cannot be determined if the dependency "of claims 1-10" is in alternative form or if this claim depends from all of claims 1-10.

14. Claim 13 recites the limitation "DNA sequence". There is insufficient antecedent basis for this limitation in the claim.

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15. Claims 3-8, 10, 12 and 14 are indefinite for being dependent from the indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claims 1-4, 6, 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bech-Hansen et al. (2000, Nature genetics, 26, pp.319-323, reference AB of the Paper No.1).

Bech-Hansen et al. disclose a cDNA molecule that has 100% identity to the SEQ ID NO:1 that encodes a human GPI-anchored small leucine-rich proteoglycan of SEQ ID NO:2 (see the sequence alignment attached to the instant office action). The protein of SEQ ID NO:2, nyctalopin, is expressed in retina and kidney (see Fig. 4a, page 321). Thus, the teachings of Bech-Hansen et al. anticipate the limitations of claims 1-4, 6 and 8-10.

Conclusion

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
March 21, 2002

OC



JOHN ULM
PRIMARY EXAMINER
GROUP 1800